General

Guideline Title

Diagnostic, monitoring, and resistance laboratory tests for HIV.

Bibliographic Source(s)

New York State Department of Health. Diagnostic, monitoring, and resistance laboratory tests for HIV. New York (NY): New York State Department of Health; 2011 Feb. 27 p. [15 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Diagnostic, monitoring, and resistance tests for HIV. New York (NY): New York State Department of Health; 2005 May. 12 p.

Recommendations

Major Recommendations

Definitions for the quality of the evidence (I, II, III) and strength of recommendation (A-C) are provided at the end of the "Major Recommendations" field.

What's New — February 2011 Update

- Table 2 in the original guideline document has been updated with the latest information regarding available rapid human immunodeficiency virus (HIV) tests, including the INSTI HIV-1 Antibody Test
- Information regarding integrase and fusion inhibitors has been updated (see Section III. C. 1. *Genotyping* in the original guideline document)
- The section on co-receptor tropism detection has been updated to include information regarding genotypic testing (see Section III. C. 3. *Co-Receptor Tropism Assay* in the original guideline document)

Diagnostic Tests

Diagnostic HIV tests must be performed in full compliance with the New York State HIV Confidentiality Law.

HIV nucleic acid testing (NAT) to detect HIV ribonucleic acid (RNA) or deoxyribonucleic acid (DNA) is recommended for establishing the diagnosis of infection in infants born to HIV-1-infected mothers. (AI) See the New York State Department of Health (NYSDoH) guideline Diagnosis of Pediatric HIV Infection in HIV-Exposed Infants for more guidance on infant testing.

Clinicians should use an HIV antibody test with confirmation by Western blot or indirect immunofluorescence assay to establish diagnosis of chronic HIV infection. HIV antibody screening tests include enzyme immunoassays (enzyme-linked immunosorbent assay [ELISA]/enzyme immunoassay [EIA]), chemiluminescent immunoassays (CIAs), and rapid tests. (AII)

Patients who test negative for HIV antibody at baseline should receive a follow-up HIV antibody test at 3 months. For individuals who test negative at 3 months but continue to engage in high-risk behavior, clinicians should discuss goal-oriented harm-reduction strategies, including referral for risk-reduction counseling services. Repeat testing at least every 3 months should be offered as long as high-risk behavior continues. (AIII)

Clinicians should evaluate the following populations for acute HIV infection, particularly when they present with a febrile, "flu"-, or "mono"-like illness that is not otherwise explained (see the NYSDoH guideline Diagnosis and Management of Acute HIV Infection):

- Those who present for HIV testing (AIII)
- Those who report a recent sexual or parenteral exposure with a known HIV-infected partner or a partner of unknown HIV serostatus in the past 2 to 6 weeks (AII)
- Men who report having unsafe sexual practices with other men (AII)
- Those who report needle-sharing (AII)
- Those who present with a newly diagnosed sexually transmitted infection (AII)
- Those who present with aseptic meningitis (AII)
- Pregnant or breast-feeding patients (AIII)

When acute HIV infection is suspected:

- An HIV serologic screening test should be used in conjunction with a plasma HIV RNA assay (AII); the plasma RNA test should be performed even if the serologic screening test is negative (AIII); a fourth-generation HIV antigen/antibody combination test is the preferred serologic screening test if available.
- Detection of HIV RNA or antigen in the absence of HIV antibody should be considered a preliminary positive result; HIV RNA testing from a new specimen should be repeated immediately to confirm the presence of HIV RNA
- Both serologic and RNA testing should be repeated to exclude a false-positive result when low-level quantitative results (<5,000 copies/mL) from an HIV RNA assay are reported in the absence of serologic evidence of HIV infection (AII).

HIV serologic testing should be repeated 2 to 3 weeks after diagnosis by HIV RNA testing to confirm infection (AII). However, clinicians should not wait for HIV serologic confirmatory test results to initiate ART when pregnant women are diagnosed with acute HIV infection by HIV RNA testing. Initiation of ART is strongly recommended for pregnant women (see the NYSDoH guideline Acute HIV Infection in Pregnancy). (AII)

Antibody Tests

Key Point:

Antibody test results that are initially negative should be followed up with HIV antibody testing at 3 months to identify HIV infection in individuals with recent exposures who may not yet have seroconverted at the time of initial presentation.

Refer to the original guideline document for discussions of specific antibody tests, including HIV-1 antibody screening assays (ELISA, home access HIV-1 test system, rapid tests, and Western Blot for screening oral fluids and urine) and HIV-1 confirmatory antibody assays (Western blot, indirect immunofluorescence assay).

HIV-2 Antibody Screening

Clinicians should screen patients who are at risk for HIV-2 infection with a test that detects HIV-2 screening antibodies (see Table 3 in the original guideline document). (AIII)

Viral Identification Assays

DNA Polymerase Chain Reaction (DNA-PCR)

HIV-1 DNA PCR should be used only for the detection of infection in infants born to mothers infected with HIV-1. (AIII)

All initial positive DNA PCRs should be confirmed with a second PCR test on a separate specimen. (AII)

Plasma HIV RNA Assays

A plasma HIV RNA assay should be used in conjunction with an HIV-1 antibody test to diagnose acute or primary HIV infection. (AII)

Monitoring Tests

Lymphocyte Analysis

Clinicians should measure CD4 cell counts at the time of diagnosis of HIV infection and every 3 to 4 months thereafter (see the "Lymphocyte Subsets" section in the NGC summary of the NYSDoH guideline Antiretroviral Therapy). (BIII)

Treatment decisions should not be made solely on the basis of a single CD4 cell measurement obtained at a single point in time. Treatment decisions should be made only after two successive measurements have been obtained. (AIII)

CD4 cell counts should not be used for diagnosis of HIV infection.

Viral Load Assays

Clinicians should repeat viral load tests that are inconsistent with the clinical presentation before management decisions are made. (AIII)

Assays that detect <50 copies/mL should be used to monitor patients who have viral loads <400 copies/mL. (BIII)

See the original guideline document for a discussion of various viral load assays, which quantify the amount of HIV-1 RNA circulating in the infected patient's blood (e.g., Roche Amplicor HIV-1 Monitor and Roche Amplicor HIV-1 Monitor Ultrasensitive, Versant HIV-1 RNA 3.0 assay, the NucliSens HIV-1 QT assay, and other tests).

Drug Resistance Tests

Clinicians should perform resistance testing under the following circumstances:

- At baseline, regardless of whether antiretroviral (ARV) therapy is being initiated (genotypic testing) (AIII)
- In ARV therapy-naive patients before initiation of ARV therapy (genotypic testing) (AII)
- In patients experiencing treatment failure or incomplete viral suppression while receiving ARV therapy (genotypic and/or phenotypic testing) (AII)

Resistance testing should be performed promptly in cases of virologic failure or incomplete viral suppression. Resistance testing should be performed while patients are still receiving therapy or have been off therapy for no more than 1 year. (AII)

Clinicians should consult with an expert to interpret the results of resistance assays because such results are often complex (the New York State AIDS Institute's Clinical Education Initiative line is available for phone consultation). (AIII)

See the original guideline document for further discussion and description of genotypic, phenotypic, and co-receptor tropism assays for testing drug resistance.

Human Leukocyte Antigen (HLA) Testing

Clinicians should perform HLA-B*5701 testing before initiating abacavir-based therapy. (AI)

Definitions:

Quality of Evidence for Recommendation

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
III. Expert opinion

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Human immunodeficiency virus (HIV, HIV-1, HIV-2) infection

Guideline Category

Counseling

Diagnosis

Evaluation

Risk Assessment

Screening

Technology Assessment

Clinical Specialty

Allergy and Immunology

Family Practice

Infectious Diseases

Obstetrics and Gynecology

Pediatrics

Intended Users

Advanced Practice Nurses

Clinical Laboratory Personnel

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

To provide an overview of currently available human immunodeficiency virus (HIV) laboratory screening methods, viral load assays, and HIV resistance tests

Target Population

- Adults and children older than eighteen months:
  - Who are at risk of acquiring human immunodeficiency virus (HIV) infection OR
  - Who have been diagnosed as being HIV infected (HIV-1 or HIV-2)
- Infants born to HIV-infected mothers

Interventions and Practices Considered

Counseling

1. Post-test counseling
2. Risk reduction counseling as indicated

Diagnostic Tests

Nucleic acid test (NAT) to diagnose infection in infants born to human immunodeficiency virus (HIV)-1 infected mothers

Antibody Tests

1. HIV-1 antibody screening assays
   - Enzyme-linked immunosorbent assays (ELISA)
   - Home access HIV-1 test system (dried blood spot)
   - Rapid tests
   - Western blot (WB) for screening oral fluid and urine
2. HIV-1 confirmatory antibody assays
   - Western blot
   - Indirect immunofluorescence assay (IFA)
3. HIV-2 antibody screening assays: combination ELISA
4. Viral identification assays
   - Deoxyribonucleic acid (DNA) polymerase chain reaction (DNA-PCR)
   - Plasma HIV ribonucleic acid (RNA)

Monitoring Tests

1. Lymphocyte analysis (CD4 percentage)
2. Viral load assays
   - Reverse transcription-polymerase chain reaction (RT-PCR)
   - Branched chain DNA (bDNA)
   - Nucleic acid sequence-based assays (NASBA)
3. Drug resistance tests
   - Genotypic assays
   - Phenotypic assays
   - Co-receptor tropism assay
4. Human leukocyte antigen testing (HLA-B*5701 testing)

Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests and screening and confirmatory assays
- Test results, including false-positive, false-negative, and indeterminate results (also known as inconclusive or nondiagnostic results)
- Absolute copy number generated (for viral load assays)
- Efficacy of tests at predicting human immunodeficiency virus (HIV) progression
- Clinical utility of resistance testing

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Not stated

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence for Recommendation

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
III. Expert opinion

Methods Used to Analyze the Evidence

Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with human immunodeficiency virus (HIV) infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

*Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Guidelines Committee
- Committee for the Care of Women with HIV Infection
- Committee for the Care of Substance Users with HIV Infection
- Physicians' Prevention Advisory Committee
- Pharmacy Advisory Committee

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

This guideline is intended to help clinicians make appropriate decisions about diagnostic, monitoring, and resistance testing for human immunodeficiency virus (HIV) in children and adults.

Potential Harms

False-positive and false-negative test results

Qualifying Statements

Qualifying Statements

When formulating guidelines for a disease as complex and fluid as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), it is impossible to anticipate every scenario. It is expected that in specific situations, there will be valid exceptions to the approaches offered in these guidelines and sound reason to deviate from the recommendations provided within.

Implementation of the Guideline

Description of Implementation Strategy

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with human immunodeficiency virus (HIV) infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers, and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative (CEI), the AIDS Educational Training Centers (AETC), and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDOH) Distribution Center.

Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the CEI and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

Implementation Tools

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2004 (revised 2011 Feb)

Guideline Developer(s)

New York State Department of Health - State/Local Government Agency [U.S.]

Source(s) of Funding

New York State Department of Health

Guideline Committee

Medical Care Criteria Committee

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: New York State Department of Health. Diagnostic, monitoring, and resistance tests for HIV. New York (NY): New York State Department of Health; 2005 May. 12 p.

Guideline Availability

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site.

Availability of Companion Documents

A series of diagrams on human immunodeficiency virus (HIV) laboratory testing are available in the appendices of the original guideline document.

Patient Resources

None available

NGC Status

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